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# **EXHIBIT 1**

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UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.

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In the Matter of )

CERTAIN MAGNETIC )

RESONANCE INJECTION )

SYSTEMS AND COMPONENTS )

THEREOF )

Investigation No. 337-TA-434

Order No. 16: Initial Determination Granting Nemoto's Motion No. 434-6 For Summary Determination And Liebel's Motion No. 434-11 For Summary Determination And Finding The '648 Patent, The Sole Patent In Issue In This Investigation, Invalid

On August 25, 2000 respondent Nemoto Kyorindo Co., Ltd. (Nemoto) moved, pursuant to Commission rule 210.18(a), for summary determination that U.S. Patent No. Re. 36,648 (the '648 patent) of complainant Medrad, Inc. (Medrad) is invalid. (Motion No. 434-6). Nemoto submitted a "Statement Of Material Facts As To Which There Is No Genuine Issue" together with Motion No. 434-6.

Nemoto, as the basis for Motion No. 434-6, argued that Medrad's failure to file a supplemental oath (or declaration) renders the '648 reissue patent invalid. In support Nemoto argued that the reissue declaration submitted by the four originally named inventors only mentioned Medrad's "underclaiming" errors, i.e., that Medrad had allegedly failed to claim its invention as fully as it was entitled. Hence it argued that in accordance with the Patent and Trademark Office (PTO) rules, this is the only issue that Medrad should have been correcting in its application for the '648 patent. In contrast, Nemoto argued that, during the prosecution of said application, Medrad "very clearly" corrected two errors, viz., an "overclaiming" error and an

"inventorship" error that were not mentioned in the declaration for the reissue application and for which Medrad did not submit the "mandatory" supplementary declaration or oath from the inventors required by PTO rule 175. Nemoto cites Nupla Corp. v. IXL Mfg. Co., 114 F.3d 191 (Fed. Cir. 1997) (Nupla) which it represented states that "failure to comply with the regulations concerning a supplemental oath or declaration renders a reissue patent invalid and this requirement is strictly enforced."

On September 11, 2000 respondents Liebel-Flarsheim Company, Mallinckrodt Inc (NY) and Mallinckrodt Inc. (Del.) (Liebel) moved, pursuant to Commission rule 210.18(a), for summary determination that the '648 patent is invalid. (Motion Docket No. 434-11). Liebel submitted a "Statement Of Material Facts As To Which There Is No Dispute" together with Motion No. 434-11.

Liebel, as the basis for its Motion No. 434-11, argued that during prosecution of the reissue proceeding resulting in the '648 patent Medrad sought to correct the inventorship of the '648 reissue patent by adding two additional inventors; that in clear violation of the rules governing reissue proceedings, Medrad sought correction through a petition to correct inventorship under rule 324 of the PTO and failed to have the newly-named inventors submit an oath or declaration that the errors being corrected in the reissue application arose without deceptive intention on their part; and that none of the named inventors in the '648 reissue patent filed a supplemental oath or declaration to cover "errors" that were corrected subsequent to the filing of the initial oath or declaration, including an overclaiming error.

The administrative law judge granted unopposed motions for extensions of time to respond to Motion No. 434-6 by both Medrad and the staff, thus extending Medrad's and the staff's

response time to close of business September 11, 2000. See Order Nos. 9 & 10. On September 11, 2000 both Medrad and the staff filed oppositions to Motion No. 434-6. Medrad, together with its opposition to Motion No. 434-6, included a "Response In Opposition To Nemoto Kyorindo Co., Ltd.'s Statement Of Material Facts" and a declaration by the attorney who prosecuted the reissue application for the '648 patent (Bradley Declaration).<sup>1</sup>

On September 13, 2000 Nemoto moved for leave to file a reply to the oppositions of the staff and Medrad on the ground that a reply is necessary due to "the fundamental misunderstanding of 37 CFR 1.175 by the Staff and due to Medrad's mischaracterization of the consequences of the lack of the supplemental oath." (Motion Docket No. 434-12). Motion No. 434-12 is granted.

The administrative law judge granted unopposed motions for extensions of time to respond to Motion No. 434-11 by Medrad, Nemoto, and the staff, thus extending Medrad's, Nemoto's, and the staff's response time to close of business September 25, 2000. See Order Nos. 13, 14, and 15.

On September 25, 2000 Medrad opposed Motion No. 434-11. Medrad filed a "Statement Of Material Facts As To Which There Is No Genuine Issue" and a "Response In Opposition To Liebel-Flarsheim Company, Mallinckrodt Inc (NY) and Mallinckrodt Inc.'s (Del.) Statement Of

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<sup>1</sup>On September 11, 2000 Liebel filed a response to Motion No. 434-6. Liebel did not file any motion for an extension of time to respond to Motion No. 434-6. Therefore, Liebel's response was due September 6. As such, Liebel's response was untimely filed and was not accompanied by a motion for leave to late file. Accordingly Liebel's response has not been considered by the administrative law judge. See also Order No. 10.

Material Facts" together with its opposition to Motion No. 434-11.<sup>2</sup> Nemoto, on September 25, supported Motion No. 434-11.

While the staff opposed Motion No. 434-6 in its opposition of September 11, 2000 and thus opposed the granting of summary determination that the '648 patent is invalid due to Medrad's failure to submit supplemental oaths with respect to the overclaiming and inventorship errors, the staff reversed its position in its response to Motion No. 434-11 filed on September 25 in which it supported summary determination of invalidity of the '648 patent due to Medrad's failure to file a supplemental oath with respect to the overclaiming error. However, the staff, in its September 25 response, opposed summary determination of invalidity of the '648 patent due to Medrad's failure to file a supplemental oath with respect to the inventorship error.

Commission rule 201.18(a) provides that "[a]ny party may move with any necessary supporting affidavits for a summary determination in his favor upon all or any part of the issues to be determined in the investigation." The administrative law judge must render a decision in favor of the moving party if the pleadings, and any depositions, answers to interrogatories, and admissions on file, together with any affidavits submitted in support of or in opposition to the motion for summary determination, show that there is no genuine issue of material fact and that the moving party is entitled to summary determination as a matter of law. See e.g. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250, (1986) (Anderson) ("the threshold inquiry of determining whether there is the need for a trial -- whether . . . there are

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<sup>2</sup>Medrad, in its opposition of September 25, 2000, stated, with respect to the argument in its opposition of September 11, that "Medrad will not repeat those arguments in detail, but incorporates them here by reference..."

any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party."). The administrative law judge must accept all evidence presented by the non-movant complainant as true, must view all of the evidence in the light most favorable to the non-movant complainant, and must draw all justifiable inferences in favor of non-movant complainant when deciding a motion for summary determination. See Anderson, 477 U.S. at 255. However, non-movant has the burden to submit more than averments in pleadings or allegations in legal memoranda to overcome a motion for summary determination. See Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986), Anderson, 477 U.S. 249-252. Mere denials or conclusory statements are insufficient. SRI International v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1116 (Fed. Cir. 1985) (SRI International). Summary determination may be properly decided as a matter of law when no genuine issue of material fact exists and no expert testimony is required to explain the nature of the patented invention or the accused product or to assist in their comparison. Amhil Enterprises Ltd. v. Wawa, Inc., 81 F.3d 1554, 1557 (Fed. Cir. 1996). The Commission has determined patent invalidity based on summary determination where there has not existed any genuine issues of material fact. See e.g. Certain Digital Satellite System (DSS) Receivers and Components Thereof, 337-TA-392 Order No. 50, Initial Determination (May 16, 1997), Notice Of Commission Determination Not To Review An Initial Determination Granting Respondents' Motion For Summary Determination That A Patent Claim Is Invalid As Anticipated Under 35 U.S.C. § 102(b) (June 18, 1997).

The administrative law judge finds that the record establishes the following material facts, which facts are either entirely undisputed by the parties, or have been modified by the

administrative law judge, with support from the record, such that any dispute is eliminated as to those facts:<sup>3</sup>

1. U.S. Patent No. Re. 36,648 (the '648 patent) is a reissue of U.S. Patent No. 5,494,036 (the '036 patent). The '648 patent is based on reissue application Ser. No. 09/027,852 filed on February 23, 1998.
2. The '036 patent issued to Arthur E. Uber III, Seid Waddell, John Stulen, and Jon E. Manley on February 27, 1996. It is based on Application Ser. No. 158,055 filed on November 26, 1993.
3. The '638 patent issued to Arthur E. Uber III, Seid Waddell, John Stulen, Jon E. Manley, Salvatore J. Dedola and Gordon C. Newell.
4. Medrad filed one certified copy of the file history of the '648 reissue patent and three copies of the certified copy with the Secretary of the U.S. International Trade Commission.
5. Medrad admits that the pages marked in the upper right hand corner with "Page" numbers 3-246 of Exhibit A to Nemoto's "Statement Of The Materials Facts As To Which There Is No Genuine Issue In Support Of Respondent Nemoto Kyorindo Co., Ltd.'s Motion For Summary Determination Of Reissue Patent Invalidity" appears to be a copy of the certified file history of the '648 reissue patent. Pages 1-2 of Exhibit A are copies of a letter dated July 10, 2000 from Arthur Wineburg to Donna R. Koehnke, Secretary of the U.S. International Trade Commission.
6. Medrad admits that the certified file history appears to contain every paper currently in the PTO file of the '648 patent.
7. The application that led to the '648 reissue patent was filed on February 23, 1998.
8. A copy of the '036 patent was among the documents submitted to the PTO on February 23, 1998 with the application for reissue.
9. An "Assent of Assignee" dated February 23, 1998 and signed by Joseph B. Havrilla was among the documents submitted to the PTO on February 23, 1998 with the application for reissue.

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<sup>3</sup>The administrative law judge's determination that there is no genuine issue of material fact with respect to Nemoto's and Liebel's contentions are based on Nemoto's Statement of Facts and Liebel's Statement Of Facts as well as Medrad's Oppositions to those Statements and the evidence of record.

10. A document entitled "Certificate Under 37 C.F.R. §3.73(b)," with Medrad named as the assignee, signed by Joseph B. Havrilla was submitted to the PTO on February 23, 1998 with the application for reissue. Exh. A, page 14.
11. A Power of Attorney appointing Gregory L. Bradley, Frederick H. Colen, Robert A. Matthews, Cheryl L. Gastineau, Henry E. Bartony and Ruth N. Morduch, dated February 23, 1998 and signed by Joseph B. Havrilla was submitted to the PTO on February 23, 1998 with the application for reissue.
12. The certified file history of the '648 patent contains a "CERTIFICATE OF MAILING BY 'EXPRESS MAIL' (37 C.F.R. 1.10)." Exh. A, page 7.
13. The Certified File History contains a copy of a Reissue Declaration executed by Arthur E. Uber III on February 17, 1998. Pages 8-11 of Exhibit A.
14. Mr. Uber declared:

We, Arthur E. Uber, III, Seid Wadell, John Stulen and Jon E. Manley, hereby declare that: our residences, post office addresses and citizenship are as stated below next to our names; we believe that we are the original, first and sole inventors of the subject matter described and claimed in U.S. Patent No. 5,494,036, granted on February 27, 1996, and for which a reissue patent is sought on the invention entitled "Patient Infusion System For Use With MRI," the specification of which is attached hereto; we have reviewed and understand the contents of the above-identified reissue application, including the new and broadened claims therein; we acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56; for the reasons provided below, we verily believe the original patent to be partly inoperative; and all errors relied upon above and corrected in this reissue application arose without any deceptive intention on our part.

We believe the original patent to be partly inoperative by reason of our claiming less than we had a right to claim in the patent. Specifically, we claimed less than we had a right to claim by failing to independently claim certain features of our invention, such as dual-syringe injector and a battery-



powered injector. Because we claimed less than we had a right to claim in the original patent, we wish to broaden the claims present in the original patent.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this Declaration is directed.

(Exh. A 8-9).

15. In addition to Mr. Uber's reissue declaration naming Messrs. Waddell, Stulen and Manley as co-inventors, Mr. Uber also signed a statement on February 9, 1999 naming Mr. Dedola and Mr. Newell as co-inventors, Exh. A, page 188:

I, Arthur E. Uber, III, have no disagreement with regard to the requested inventorship change of including Messrs. Salvatore J. Dedola and Gordon C. Newell as inventors of the above-identified reissue application.

16. The file history contains a copy of a declaration executed by Mr. Waddell on February 14, 1998.
17. Mr. Waddell declared:

We, Arthur E. Uber, III, Seid Wadell, John Stulen and Jon E. Manley, hereby declare that: our residences, post office addresses and citizenship are as stated below next to our names; we believe that we are the original, first and sole inventors of the subject matter described and claimed in U.S. Patent No. 5,494,036, granted on February 27, 1996, and for which a reissue patent is sought on the invention entitled "Patient Infusion System For Use With MRI," the specification of which is attached hereto; we have reviewed and understand the contents of the above-identified reissue application, including the new and broadened claims therein; we acknowledge the duty to disclose information which is

material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56; for the reasons provided below, we verily believe the original patent to be partly inoperative; and all errors relied upon above and corrected in this reissue application arose without any deceptive intention on our part.

We believe the original patent to be partly inoperative by reason of our claiming less than we had a right to claim in the patent. Specifically, we claimed less than we had a right to claim by failing to independently claim certain features of our invention, such as dual-syringe injector and a battery-powered injector. Because we claimed less than we had a right to claim in the original patent; we wish to broaden the claims present in the original patent.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this Declaration is directed.

(Exh. A, 8-9).

18. In addition to Mr. Waddell's reissue declaration naming Messrs. Uber, Stulen and Manley as co-inventors, Mr. Waddell also signed a statement on February 6, 1999 naming Messrs. Dedola and Newell as co-inventors, Exh. A, page 190:

I, Seid Waddell, have no disagreement with regard to the requested inventorship change of including Messrs. Salvatore J. Dedola and Gordon C. Newell as inventors of the above-identified reissue application.

19. Medrad admits that John Stulen signed a reissue declaration on February 18, 1998.
20. Mr. Stulen declared:

We, Arthur E. Uber, III, Seid Wadell, John Stulen and Jon E. Manley, hereby declare that: our residences, post office addresses and citizenship are as stated below next to our names; we believe that we are the original, first and sole inventors of the subject matter described and claimed in U.S. Patent No. 5,494,036, granted on February 27, 1996, and for which a reissue patent is sought on the invention entitled "Patient Infusion System For Use With MRI," the specification of which is attached hereto; we have reviewed and understand the contents of the above-identified reissue application, including the new and broadened claims therein; we acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56; for the reasons provided below, we verily believe the original patent to be partly inoperative; and all errors relied upon above and corrected in this reissue application arose without any deceptive intention on our part.

We believe the original patent to be partly inoperative by reason of our claiming less than we had a right to claim in the patent. Specifically, we claimed less than we had a right to claim by failing to independently claim certain features of our invention, such as dual-syringe injector and a battery-powered injector. Because we claimed less than we had a right to claim in the original patent, we wish to broaden the claims present in the original patent.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this Declaration is directed.

(Exh. A, 8-9).

21. In addition to Mr. Stulen's reissue declaration naming Messrs. Waddell, Uber

and Manley as co-inventors, Mr. Stulen also signed a statement on February 17, 1999 naming Messrs. Dedola and Newell as co-inventors, Exh. A, page 183:

I, John Stulen, have no disagreement with regard to the requested inventorship change of including Messrs. Salvatore J. Dedola and Gordon C. Newell as inventors of the above-identified reissue application.

22. The Certified File History contains a copy of a reissue declaration executed by Jon E. Manley on February 20, 1998. Pages 8-12 of Exh. A.
23. Mr. Manley declared:

We, Arthur E. Uber, III, Seid Wadell, John Stulen and Jon E. Manley, hereby declare that: our residences, post office addresses and citizenship are as stated below next to our names; we believe that we are the original, first and sole inventors of the subject matter described and claimed in U.S. Patent No. 5,494,036, granted on February 27, 1996, and for which a reissue patent is sought on the invention entitled "Patient Infusion System For Use With MRI," the specification of which is attached hereto; we have reviewed and understand the contents of the above-identified reissue application, including the new and broadened claims therein; we acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56; for the reasons provided below, we verily believe the original patent to be partly inoperative; and all errors relied upon above and corrected in this reissue application arose without any deceptive intention on our part.

We believe the original patent to be partly inoperative by reason of our claiming less than we had a right to claim in the patent. Specifically, we claimed less than we had a right to claim by failing to independently claim certain features of our invention, such as dual-syringe injector and a battery-powered injector. Because we claimed less than we had a right to claim in the original patent, we wish to broaden the claims present in the original patent.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this Declaration is directed.

(Exh. A, 8-9).

24. In addition to Mr. Manley's reissue declaration naming Messrs. Waddell, Stulen and Uber as co-inventors, Mr. Manley also signed a statement on February 7, 1999 naming Messrs. Dedola and Mr. Newell as co-inventors:

I, Jon E. Manley, have no disagreement with regard to the requested inventorship change of including Messrs. Salvatore J. Dedola and Gordon C. Newell as inventors of the above-identified reissue application.

25. The reissue application was filed on February 23, 1998. That filing consisted of a preliminary amendment that added five patent references and new claims 24-49; declarations of the inventors; and an Information Disclosure Statement listing 12 U.S. patents, seven foreign patent documents, and two articles. Exh. A, pages 7-38.

26. The February 23, 1998 Preliminary Amendment presented, among other things, new claim no. 24 reading as follows, Exh. A, page 30:

24. A patient infusion system for use with a magnetic resonance imaging system, the patient infusion system comprising:

an infusion apparatus positioned within a room shielded from electromagnetic interference, the infusion apparatus comprising an injector adapted to accommodate at least two syringes mounted thereon for injecting fluid into a patient during a magnetic resonance imaging procedure; and

a system controller positioned external to the shielded room and in communication with the infusion apparatus for controlling the operation thereof.

27. The February 23, 1998 preliminary amendment filed with the reissue application presented, among other things, new independent claim 32 which claimed as follows, Exh. A, page 31:

32. A patient infusion system for use with a magnetic resonance imaging system, the patient infusion system comprising:

an infusion apparatus positioned within a room shielded from electromagnetic interference, the infusion apparatus comprising an injector for injecting fluid into a patient during a magnetic resonance imaging procedure and a control unit comprising a battery for powering the injector and minimizing electromagnetic interference with the magnetic resonance imaging system; and

a system controller positioned external to the shielded room and in communication with the infusion apparatus for controlling the operation thereof.

28. On November 13, 1998, Mr. Bradley received a telephone call from Examiner Casler advising that the Examiner was sending to him by facsimile an outline of proposed rejections of the reissue claims for discussion purposes. Exh. A, page 226.
29. The only written record of his call to Mr. Bradley explaining a fax was forthcoming was made by the Examiner's note.
30. On November 13, 1998, Examiner Casler faxed to Mr. Bradley what he identified as a "broad outline" of the proposed rejections of the claims solely for discussion purposes prior to actually issuing an Office Action. Exh. A, page 225.
31. The Examiner's notice specifically indicated that his fax was for discussion purposes. Exh. A, page 225.
32. On November 22, 1998, Mr. Bradley sent to Examiner Casler by facsimile a document entitled "DRAFT CLAIMS FOR DISCUSSION PURPOSES DURING EXAMINER INTERVIEW ON 11/24/98." On the cover sheet accompanying the draft claims for discussion purposes, Mr. Bradley wrote in an effort to advance prosecution: "At this time I am inclined to agree with your proposed rejections of claims 1-6 and 22." Exh. A, page 114; Bradley Dec.
33. On November 24, 1998, Messrs. Bradley and Dedola had a personal interview with Examiner Casler. Exh. A, page 113.

34. In the interview summary of the November 24, 1998 interview, Examiner Casler stated: "The Examiner and the applicants discussed possible changes to overcome the prior art. Upon receiving a proposed amendment, the Examiner agrees to further review the prior art in view of the proposed changes." Exh. A, page 113.
35. On December 18, 1998, Mr. Bradley had a telephone interview with Examiner Casler. This was after Mr. Bradley proposed a preliminary amendment to the Examiner on November 25, 1998. Exh. A, pages 127-34.
36. In the Interview Summary of the December 18, 1998 interview, Examiner Casler stated that it was not necessary for Medrad "to provide a separate record of the substance of the interview." Page 127 of Exh. A. In addition, the Examiner commented in the interview summary that "the Examiner and the applicant agreed on language for a preliminary amendment. The Examiner will continue to review any proposed claims submitted by the applicant and discuss any rejections applicable thereto, to advance prosecution of the case." Exh. A, page 127.
37. Mr. Bradley sent a "Supplemental Amendment" by facsimile on December 18, 1998, after the telephone interview. Exh. A, pages 136-42.
38. The December 18, 1998 "Supplemental Amendment" amended claim 1 by adding limitation d) which recited "at least one battery for powering the motor control circuitry and the electric drive motor and for minimizing electromagnetic interference with magnetic resonance imaging apparatus." Pages 136-137 of Exh. A.
39. The December 18, 1998 "Supplemental Amendment" amended claim 22 by adding to limitation b) the recitation "and motor control circuitry, at least one battery for powering the motor control circuitry and the at least one motor and for minimizing electromagnetic interference with the magnetic resonance imaging system." Page 139 of Exh. A.
40. On January 4, 1999, Examiner Casler mailed an office action dated December 20, 1998. Exh. A, pages 145-50.
41. At the time Examiner Casler issued the January 4, 1999 Office Action, there were 45 claims pending in the Reissue Application, namely claims 1-40, 44, 45, and 47-49. Page 145 of Exh. A.
42. In the January 4, 1999 Office Action, Examiner Casler (a) allowed claims 8, 23-31 and 40; (b) indicated that claims 10-12, 14-16 and 48-49 would be allowable if rewritten in independent form; and (c) rejected claims 1-7, 9, 13, 17-22, 32-39, 44-45, and 47. Exh. A, pages 145-50.

43. In the February 23, 1999 response and amendment, Medrad cancelled claims 1-7 and 22 "without prejudice to presenting them in this or a later-filed continuing application," and without acquiescing in the rejection. Exh. A, page 203.
44. Medrad traversed the rejection of claims 9 and 13, but amended those claims for clarification. Exh. A, page 204.
45. On February 23, 1999, Medrad first sought to correct inventorship of the reissue application based on the '036 patent by filing a petition to correct inventorship under 37 C.F. R. §1.324. Accompanying that petition were statements from Messrs. Dedola and Newell that the inventorship error occurred without deceptive intention; statements from the inventors Uber, Manley, Stulen and Waddell that they did not disagree with the inventorship change; and a statement from Medrad, the assignee, agreeing to the change of inventorship. Exh. A, pages 178-95.
46. Medrad's February 23, 1999 Petition To Correct Inventorship included a statement from Arthur E. Uber III that he did not disagree with the change in inventorship. Page 188 of Exh. A.
47. Mr. Uber's statement identified the change of inventorship as adding Messrs. Dedola and Newell as inventors of the reissue application. Exh. A, page 188.
48. Medrad's February 23, 1999 Petition To Correct Inventorship included a statement from Seid Waddell that he did not disagree with the change in inventorship. Page 190 of Exh. A.
49. Mr. Waddell's statement identified the change of inventorship as adding Messrs. Dedola and Newell as inventors of the reissue application. Exh. A, page 190.
50. Medrad's February 23, 1999 Petition To Correct Inventorship included a statement from John Stulen that he did not disagree with the change in inventorship. Page 183 of Exh. A.
51. Mr. Stulen's statement identified the change of inventorship as adding Messrs. Dedola and Newell as inventors of the reissue application. Exh. A, page 183.
52. Medrad's February 23, 1999 Petition To Correct Inventorship included a statement from Jon E. Manley that he did not disagree with the change in inventorship. Page 189 of Exh. A.
53. Mr. Manley's statement identified the change of inventorship as adding Messrs.



Dedola and Newell as inventors of the reissue application. Exh. A, page 189.<sup>4</sup>

PTO rule 175, as applicable when Medrad filed its reissue application, reads:

(a) The reissue oath or declaration in addition to complying with the requirements of §1.63, must also state that:

(1) The applicant believes the original patent to be wholly or partly inoperative or invalid by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than the patentee had a right to claim in the patent, stating at least one error being relied upon as the basis for reissue; and

(2) All errors being corrected in the reissue application up to the time of filing of the oath or declaration under this paragraph arose without any deceptive intention on the part of the applicant.

(b)(1) For any error corrected, which is not covered by the oath or declaration submitted under paragraph (a) of this section, applicant must submit a supplemental oath or declaration stating that every such error arose without any deceptive intention on the part of the applicant. Any supplemental oath or declaration required by this paragraph must be submitted before allowance and may be submitted:

(i) With any amendment prior to allowance; or

(ii) In order to overcome a rejection under 35 U.S.C. 251 made by the examiner where it is indicated that the submission of a supplemental oath or declaration as required by this paragraph will overcome the rejection.

(2) For any error sought to be corrected after allowance, a supplemental oath or declaration must accompany the requested correction stating that the error(s) to be corrected arose without any deceptive intention on the part of the applicant.

(c) Having once stated an error upon which reissue is based, as set forth in paragraph (a)(1), unless all errors previously stated in the oath or declaration are no longer being corrected, a subsequent oath or declaration under paragraph (b) of this section need not specifically

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<sup>4</sup>The numbers attributed to each established fact do not correspond to any numbered facts presented in Nemoto's or Liebel's Statement of Facts or Medrad's Oppositions to those Statements.

identify any other error or errors being corrected.

(d) The oath or declaration required by paragraph (a) of this section may be submitted under the provisions of §1.53(f).

(Emphasis added).

The administrative law judge agrees with arguments of Medrad and the staff that PTO rule 175(a)(1) and (2) only requires that applicant specify "at least one error being relied upon as the basis for reissue" (Emphasis added). It is clear that the reissue declaration submitted by the original inventors identifies a required one error sought to be corrected by reissue. Thus, the original inventors declared that:

We believe the original patent to be partly inoperative by reason of our claiming less than we had a right to claim in the patent. Specifically, we claimed less than we had a right to claim by failing to independently claim certain features of our invention, such as dual-syringe injector and a battery-powered injector. Because we claimed less than we had a right to claim in the original patent, we wish to broaden the claims present in the original patent.

(Established Facts Numbered 14, 17, 20, and 23, supra) (Emphasis added). Moreover, it is clear that the one error the applicant identified is the underclaiming error.

However, the administrative law judge rejects the argument of Medrad that the initial reissue declaration covered the overclaiming and inventorship errors because "the reissue declaration that the four original inventors signed stated that 'all errors' to be corrected in the reissue application occurred without any deceptive intention." In the initial reissue declaration the original inventors declared:

[W]e have reviewed and understand the contents of the above-identified reissue application, including the new and broadened claims therein; we acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section

1.56; for the reasons provided below, we verily believe the original patent to be partly inoperative; and all errors relied upon above and corrected in this reissue application arose without any deceptive intention on our part.

(Established Facts Numbered 14, 17, 20, and 23, supra) (Emphasis added). Thus, the initial reissue declaration specifically limited itself to "all errors relied upon above" (Emphasis added). The administrative law judge finds the only error relied upon above is the underclaiming error.

Medrad argued in its opposition, filed on September 11, 2000 over some 30 months after the filing of the reissue application on February 23, 1998, that the prosecuting attorney, Mr. Bradley, at the time of filing said reissue application submitted with the reissue application an Information Disclosure Statement identifying references that came to Medrad's attention after the '036 patent issued; that Bradley "thought" the Examiner "might" consider those references relevant to patentability; that "if the examiner required amendments to overcome prior art— as he in fact did— those amendments would be correcting 'overclaiming errors' in the original patent;" and that therefore, when filing the reissue application Bradley "contemplated" the possibility that some claims might be narrowed. In making that contention, Medrad relied upon Bradley's declaration, signed September 11, 2000 and filed with Medrad's opposition to Motion No. 434-6, in which Bradley declared:

I prepared the reissue declaration under the new rules to cover any new or amended claims that would come out of the reissue process, whether considered broader, narrower, or in any way different in scope, as well as any other related corrections, such as changes in inventorship that are sometimes required when claims are added, deleted and/or amended.

(Bradley Declaration ¶10, Emphasis in original).

The administrative law judge finds that Bradley's after the fact declaration that he prepared

the reissue declaration to cover "any" new or amended claims or related correction does not alter the contents of the initial reissue declaration which only relied upon the underclaiming error. Thus, the administrative law judge finds that whether or not the prosecuting attorney Bradley, at the time of the reissue application, "contemplated" that overclaiming errors or an inventorship error would be corrected by the reissue is of no consequence.<sup>5</sup> It is the reissue declaration itself which determines compliance with PTO rule 175, not Bradley's after the fact attested to "contemplation."

As seen supra, the initial reissue declaration, at the time of the filing of the reissue application, only mentions the underclaiming error as a basis for which applicants sought reissue. Moreover, the initial reissue declaration specifically addressed the inventorship issue and stated that the original inventors were the sole inventors. Thus, in the initial reissue declaration the original inventors specifically declared "we believe that we are the original, first and sole inventors of the subject matter described and claimed in U.S. Patent No. 5,494,036" (Facts 14, 17, 20 and 23) (Emphasis added). Thus, there is no indication by Bradley or the original inventors at the time of filing the reissue application on February 23, 1998 that any of them even "contemplated" the inventorship error. In fact, the issue of inventorship does not appear in the reissue application until it was raised by the Examiner in the Interview Summary he prepared following the interview on January 21, 1999, nearly one year after Medrad filed its reissue application. (Exh. A at 176). Based on the foregoing, the administrative law judge finds that the initial reissue declaration only covered the underclaiming error.

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<sup>5</sup>Neither Bradley nor the inventors at the time of the filing of the reissue application on February 23, 1998 made any statement to the PTO that the references cited in said Information Disclosure Statement would result in any overclaiming.

Established facts numbered 28-40 demonstrate that Medrad filed supplemental amendments to the reissue application in order to overcome rejections based on prior art, thus correcting an overclaiming error. This overclaiming error was not listed in the initial declaration as a cause for reissue. As such Medrad was obligated, pursuant to PTO rule 175(b), which is an independent requirement of PTO rule 175, to file a supplemental declaration regarding the overclaiming error stating that such error was made without deceptive intent. The established facts demonstrate that no such supplemental declaration was filed by Medrad. Accordingly, the administrative law judge finds that Medrad did not comply with PTO rule 175(b) with respect to the overclaiming error in the reissue of the '648 patent.

Established fact numbered 45 shows that on February 23, 1999 Medrad first sought to correct inventorship of the reissue application based on the '036 patent by filing a petition to correct inventorship under PTO rule 324. Said petition stated that "Applicants hereby petition to correct the inventorship of the above-identified reissue application by including Messrs. Salvatore J. Dedola and Gordon C. Newell as inventors thereof." (Exh. A, at 178). Accompanying that petition were statements from Messrs. Dedola and Newell that the inventorship error occurred without deceptive intention; statements from the original inventors Uber, Manley, Stulen and Waddell that they did not disagree with the inventorship change; and a statement from Medrad, the assignee, agreeing to the change of inventorship (Fact 45). While the original inventors filed statements with the petition to correct inventorship stating that they did not disagree with the change in inventorship, the established facts show that said statement was not an oath or declaration in which the original inventors declared that the inventorship error occurred without any deceptive intention. Thus, for example, the statement of John Stulen reads as follows:

I, John Stulen, have no disagreement with regard to the requested inventorship change of including Messrs. Gordon C. Newell and Salvatore J. Dedola as inventors of the above-identified reissue application.

(Exh. A. at 183). Each of the statements by the other named inventors have the same language. (Exh. A 178-195). Said statement does not address deceptive intention as required by PTO rule 175(b). Moreover, said statement does not comply with PTO rule 175 and PTO rule 68 which requires that the declarant be warned, on the same document, that willful false statements and the like are punishable by fine and or imprisonment, or both, pursuant to 18 U.S.C. 1001. PTO rule 68 also requires that the declarant set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true. As stated supra, Medrad was obligated, pursuant to PTO rule 175(b) to file a supplemental declaration (or oath) regarding any error not covered by the initial reissue declarations stating that such error was made without deceptive intent. Accordingly, the administrative law judge finds that Medrad did not comply with Commission rule 175(b) with respect to the inventorship error corrected in the reissue.

Medrad, in its opposition filed on September 11, 2000, argued that "determining the proper vehicle for correcting inventorship proved to be somewhat problematical;" that "Examiner Casler and Mr. Bradley were uncertain as to the procedure to be followed in correcting inventorship in the reissue application;" and that "it was therefore agreed to proceed by a petition to correct inventorship under 37 C.F.R. §1.324." (Opposition at 7, citing Bradley Declaration ¶ 21-25). Whether or not the prosecuting attorney thought the issue of correcting inventorship was "problematical," he was aware of, or should have been aware of, PTO rule 175, applicable at the

time of filing the reissue application on February 23, 1998, which clearly requires a supplemental oath or declaration with respect to any error sought to be corrected that was not covered by the initial oath or declaration at the time of the filing of the reissue application. The fact that Medrad sought to correct inventorship in the reissue application by filing a petition to correct inventorship under PTO rule 324 did not obviate Medrad's obligations under PTO rule 175.

The administrative law judge finds relevant the Federal Circuit's decision in Nupla. The Court held that where a party fails to comply with PTO rule 175 with respect to the filing of supplemental declarations, the reissue patent is invalid. The Court stated:

We therefore hold, based on the principle announced in Constant and the explicit requirements of 37 C.F.R. 1.175(a)(3), (5), and (6), that when amendments correcting an overclaiming are made during reissue prosecution in response to a rejection, a patentee is obligated to file a supplementary declaration...

Nupla, 114 F.3d at 195.<sup>6</sup> While Nupla was based on an older version of PTO rule 175 which required applicant to identify all errors sought to be corrected by reissue, the administrative law judge finds that the principle enunciated by Nupla and Constant, viz., failure to comply with PTO rule 175 renders the reissue patent invalid, remains applicable.

The administrative law judge rejects the argument of Medrad, in its opposition of

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<sup>6</sup>The Court cited In re Constant, 827 F.2d 728, 729 (Fed. Cir. 1987) (Constant) and stated:

In Constant, this court affirmed the decision of the United States Patent and Trademark Office, Board of Patent Appeals and Interferences which affirmed the examiner's rejection of a reissue application on the ground that it failed to comply with 37 C.F.R. 1.175

Nupla at 193 (Emphasis added).

September 11, 2000, that the PTO did not require a supplemental declaration and that the Examiner deemed the materials filed with the reissue application sufficient. Contrary to Medrad's argument, PTO rule 175(b), as seen supra, did require Medrad to file a supplemental declaration.

As stated supra, the staff supported Motion No. 434-11 for invalidity of the '648 patent with respect to the failure of Medrad to file a supplemental oath regarding the overclaiming error and argued that "Respondents are entitled to a summary determination that claim 9 is invalid as a matter of law based on Medrad's failure to comply with Patent Office Rule 1.175." The staff, however, rejected Liebel's arguments that the '648 patent is invalid for failure to file a supplemental oath with respect to the inventorship error, which position of the staff is consistent with the position of the staff in its September 11 opposition to Motion No. 434-6. In rejecting Liebel's arguments, the staff, in its response on September 25, argued that Medrad permissibly corrected the inventorship error under PTO rule 324; that the original '036 patent remained in effect until the issue of the '648 reissue patent; that, therefore, Medrad was seeking to correct, under PTO rule 324, the issued parent '036 patent; and that there is no rule, statute or case law that would prohibit the use of PTO rule 324 to correct inventorship error of an issued patent during prosecution of a reissue patent.<sup>7</sup> The administrative law judge rejects the staff's arguments

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<sup>7</sup>The staff, in its opposition on September 11, 2000, argued that while MPEP §1412.04 currently does not permit an applicant to use PTO rule 324 to correct inventorship in a reissue application, said section of the MPEP was not applicable at the time of the filing of the reissue application. The administrative law judge agrees with the staff that the MPEP, at the time of the filing of the reissue application, did not address the procedure to correct inventorship in a reissue application. However, the fact that the MPEP did not address the procedure to correct inventorship in a reissue application does not give applicant license to ignore the requirements of PTO rule 175(b). Moreover, the MPEP does not have the force and effect of law. See Molins, PLC v. Textron, Inc., 48 F.3d 1172, 1180 (Fed. Cir. 1995); and Litton Sys. V. Whirlpool Corp., 728 F.2d 1423, 1439 (Fed. Cir. 1984).



that the '648 patent is not invalid for failure to submit a supplemental oath as to the inventorship error. While the staff argued that there is no rule, statute or case law that would prohibit the use of PTO rule 324 to correct inventorship of an issued patent during prosecution of a reissue patent, there also is no rule, statute or case law that would permit Medrad to circumvent the independent requirements of PTO rule 175(b).<sup>8</sup>

Motion Nos. 434-6 and 434-11 are granted.

Based on the foregoing, the administrative law judge finds that each of Nemoto and Liebel has sustained its burden in establishing, through clear and convincing evidence; that Medrad failed to comply with PTO rule 175(b)(1) in the reissue of the '648 patent through Medrad's failure to submit a supplemental oath or declaration before allowance of the claims in the reissue application and that there is no genuine issue of material fact on that issue. See Anderson supra. As such, the administrative law judge finds that the '648 patent is invalid.

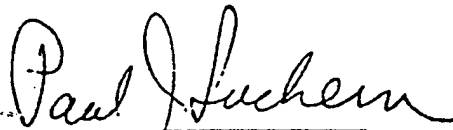
This initial determination is hereby CERTIFIED to the Commission. Pursuant to Commission rules 210.42(c) and 210.42(h)(3), this initial determination shall become the determination of the Commission within thirty (30) days after the date of service hereof unless the Commission, within 30 days after the date of such service, shall have ordered review of the initial determination of certain issues therein or by order has changed the effective date of

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<sup>8</sup>The administrative law judge also notes that, contrary to the staff's argument that Medrad sought to correct the parent '036 patent by its petition to correct inventorship under PTO rule 324, said petition specifically sought to correct inventorship of the reissue application. Thus, the caption of the petition to correct inventorship reads "In re Reissue application of UBER et. al.," and the first paragraph of the petition states "[a]pplicants hereby petition to correct the inventorship of the above identified reissue application by including Messrs. Salvatore J. Dedola and Gordon C. Newell as inventors thereof." (Exh. A at 178, Emphasis added).

initial determination of certain issues therein or by order has changed the effective date of the initial determination.<sup>9</sup>

A public version of this Order will issue unless a bracketed confidential version is received no later than October 6, 2000.



Paul J. Luckern  
Administrative Law Judge

Issued: September 26, 2000

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<sup>9</sup>The hearing in this investigation is set to commence on December 4, 2000. The fact that this Initial Determination finds the '648 reissue patent invalid does not alter said hearing date. The parties should continue to prepare for said hearing. It is only upon final disposition by the Commission that the '648 reissue patent is invalid that the parties may assume that the hearing date set would no longer apply.

**CERTAIN MAGNETIC RESONANCE INJECTION  
SYSTEMS COMPONENTS THEREOF**

**Investigation No. 337-TA-434**

**CERTIFICATE OF SERVICE**

I, Donna R. Koehnke, hereby certify that the attached Order was served by hand upon James B. Coughlan, Esq., and upon the following parties via first class mail, and air mail where necessary, on October 17, 2000.



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**CERTAIN MAGNETIC RESONANCE INJECTION  
SYSTEMS COMPONENTS THEREOF**

**Investigation No. 337-TA-434**

**CERTIFICATE OF SERVICE - p. 2**

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**CERTAIN MAGNETIC RESONANCE INJECTION  
SYSTEMS, COMPONENTS THEREOF**

**Investigation No. 337-TA-434**

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